

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION)	
)	MDL NO. 1203
)	
THIS DOCUMENT RELATES TO:)	
)	
SHEILA BROWN, et al.)	
)	CIVIL ACTION NO. 99-20593
)	
v.)	
)	
AMERICAN HOME PRODUCTS CORPORATION)	2:16 MD 1203
)	

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8606

Bartle, C.J.

February 13, 2011

Terri Zinnikas ("Ms. Zinnikas" or "claimant"), a class member under the Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth, Inc.,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether she has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. John Zinnikas, claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2003, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Robert E. Fowles, M.D., F.A.C.C. Based on an echocardiogram dated September 12, 2002, Dr. Fowles attested in Part II of claimant's Green Form that Ms. Zinnikas suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial

3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

dimension.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$496,153.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Marcus Brann, M.D., F.A.C.C., F.A.C.P., stated that "[t]he mitral valve is anatomically normal but demonstrates moderate regurgitation." He calculated claimant's RJA/LAA ratio to be "28%." Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA"). See Settlement Agreement § I.22. Dr. Brann also stated that claimant had "mildly elevated pulmonary artery systolic pressure based upon a right atrial pressure of 10." Under the Settlement Agreement, pulmonary hypertension secondary to moderate or greater mitral regurgitation is defined as peak systolic artery pressure greater than 40 mm Hg measured by cardiac catheterization or greater than 45 mm Hg measured by Doppler Echocardiography, at rest, utilizing standard procedures assuming

4. Dr. Fowles also attested that claimant suffered from mild aortic regurgitation and New York Heart Association Functional Class II symptoms. These conditions, however, are not at issue in this claim.

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Pulmonary hypertension secondary to moderate or greater mitral regurgitation and an abnormal left atrial dimension are two of the five complicating factors. See id. §§ IV.B.2.c.(2)(b)i) & ii).

a right atrial pressure of 10 mm Hg. See id.

§ IV.B.2.c.(2)(b)i). Finally, Dr. Brann stated that claimant had "mild left atrial enlargement." He noted that both the left atrial supero-inferior systolic dimension and the antero-posterior systolic dimension were 54 mm. The Settlement Agreement defines an abnormal left atrial dimension as a left atrial supero-inferior systolic dimension greater than 5.3 cm in the apical four chamber view or a left atrial antero-posterior systolic dimension greater than 4.0 cm in the parasternal long axis view. See id. § IV.B.2.c.(2)(b)ii).

In August, 2006, the Trust forwarded the claim for review by Craig M. Oliner, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had moderate mitral regurgitation:

There is mild [mitral regurgitation]. The RJA'S are freeze frames that appear to represent very early systolic back-flow and other non-[mitral regurgitant] low velocity signal. Nyquist is borderline low at 51cm/sec. Color gain is excessive, with chamber saturation. The [mitral regurgitation] is trace on the [parasternal long axis] view.

Dr. Oliner also determined that there was no reasonable medical basis for the attesting physician's finding of pulmonary hypertension secondary to moderate or greater mitral regurgitation. He noted that:

The TR velocity suggests pulmonary pressure is <45mm Hg. The [mitral regurgitation] is mild.

Finally, Dr. Oliner concluded that there was no reasonable medical basis for the attesting physician's finding that claimant had an abnormal left atrial dimension:

The [left atrium] is visually and quantitatively normal in size. The measured [supero-inferior] dimension is diagonal to the [left atrium] and includes pulmonary vein.

Based on Dr. Oliner's findings, the Trust issued a post-audit determination denying the claim. Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.⁶ In contest, claimant asserted: "[w]e believe the Green Form previously submitted to the Trust provides a reasonable medical basis for a claim with respect to medical conditions required for a matrix claim."

The Trust then issued a final post-audit determination again denying the claim. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why this claim should be paid. On February 15, 2007,

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to this claim.

we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 6971 (Feb. 15, 2007). Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 17, 2007. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for the attesting physician's findings that she had moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial dimension. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answers in claimant's Green Form that are at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answers, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, claimant simply states that she "disagrees with the medical findings of the Auditing Cardiologist and the Trust's characterization of those medical findings." The Trust responds that claimant cannot prevail

because she did not rebut Dr. Oliner's conclusion that the echocardiogram was improperly performed and interpreted.

After reviewing the entire Show Cause Record, we find that claimant does not adequately contest Dr. Oliner's diagnosis that claimant has only mild mitral regurgitation. Dr. Oliner identified numerous deficiencies in the echocardiogram of attestation, including excessive color gain, improper characterization of backflow as mitral regurgitation, and improper inclusion of low velocity flow in determining the level of claimant's mitral regurgitation. Claimant does not rebut these findings or the auditing cardiologist's conclusions regarding pulmonary hypertension secondary to moderate or greater mitral regurgitation and claimant's left atrial dimension.

Despite the opportunity in the contest period to present additional evidence in support of her claim, Ms. Zinnikas rests only on the answers of Dr. Fowles in the Green Form. Claimant never identified any error in the auditing cardiologist's conclusions. Mere disagreement with the auditing cardiologist without identification of specific errors is insufficient to meet claimant's burden of proof.

Moreover, the echocardiogram on which claimant's Green Form is based does not provide a reasonable medical basis for the attesting physician's answers. As we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly

supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation. See PTO No. 2640 at 9-13, 15, 21-22, 26 (Nov. 14, 2002). Here, Dr. Oliner determined in audit, and Ms. Zinnikas does not dispute, that claimant's level of mitral regurgitation was overestimated as a result of the manipulation of echocardiogram settings (i.e., excessive color gain), backflow was mischaracterized as mitral regurgitation, and low velocity flow was included in determining the level of claimant's mitral regurgitation. Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she had moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, and an abnormal left atrial dimension. Therefore, we will affirm the Trust's denial of the claim of Ms. Zinnikas for Matrix Benefits and the related derivative claim submitted by her spouse.